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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WARE, TODD	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,569	LUHN, OLIVER	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time (granted) and amendment both filed 2-5-03 is acknowledged. Claims 1-10 have been canceled and new claims 11-22 have been added. Claims 11-22 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 11-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These claims are omnibus type claims.

4. Claim 15 is indefinite since while it recites "consisting of" language for the granules of lactose and starch, the test B claim 15 refers to requires granules that also have magnesium stearate. Accordingly, the granules claimed in claim 15 are not those of test B and the tabletting capacity determined by test B is not coincident or commensurate with the claim.

Response to Arguments

5. Applicant's arguments filed 2-5-03 have been fully considered but they are not persuasive. Applicant argues that the material believed to cause the claims to be

omnibus claims has been canceled. This is not found persuasive. The instant claims do not satisfy 35 U.S.C. 112, second paragraph, because they do not themselves define the invention, but rely on external material. *Ex parte Fressola*, 27 USPQ2d 1608 (BPAI, 1993); MPEP 2173.05(r).

6. Applicant also argues that instant claim 15 overcomes the previous objection to previous claim 4, since it is now an independent claim. However, Applicant has not addressed the issue that "a Test B" requires magnesium stearate in the formulation, while the claim recites "consisting of" for only lactose and starch. Accordingly, the scope of the claim can not be determined.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al (5,618,562; hereafter '562).

10. '562 teaches spherical spray dried lactose and starch granules. The ratio of lactose to starch is within that of the instant claims and the angle of repose of '562 is within that of the instant claims. '562 does not specifically teach the functional limitations of the instant claims. However, '562 teaches increasing bulk density to increase hardness and reduction of surface unevenness and angular protrusions to increase the bulk density.

11. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to increase the bulk density with the motivation of increasing the harness of '562. It is noted that the instant claims recite "consisting of" language. However, omission of a step or an element is obvious if the function of the element is not desired (MPEP 2144.04(II)), *In re Kuhle* 188 USPQ 7, *In re Wilson* 156 USPQ 740.

Response to Arguments

12. Applicant's arguments filed 2-5-03 have been fully considered but they are not persuasive. Applicant argues that the instant claims are allowable over '562 on the basis that '562 "requires that the granules contain 95% by weight or more of lactose." This argument is not found persuasive. In example five, '562 teaches an embodiment within the instant claimed range, where 800 grams of lactose are combined with 100 grams of starch to give a lactose/starch ratio of 80/10. Furthermore, a teaching of 95% lactose is also considered to be obvious on the basis that a *prima* facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but

are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp of America v. Banner*, 227 USPQ 773 (Fed. Cir. 1985); MPEP 2144.05. Applicant's comments regarding page 5 of the instant specification are therefore not persuasive in the absence of data.

13. Applicant also argues that '562 does not teach the instant process of co-spray-drying the lactose with the starch and that it instead teaches a method of granulation in a fluidized bed. This argument is not found persuasive. '562 teaches co-spraying the lactose and starch in an air flow, effectively drying the ingredients (i.e. spray drying). Furthermore, Example 4 of the instant specification on page 13 demonstrates a comparative example where the granules of the instant claims are produced with a fluidized bed granulator to provide granules with the instant properties. Accordingly, spray drying is not different (is not critical) over granulation in a fluidized bed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
May 1, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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